

AMENDED IN SENATE AUGUST 7, 2006

AMENDED IN SENATE JUNE 19, 2006

AMENDED IN ASSEMBLY MAY 8, 2006

AMENDED IN ASSEMBLY APRIL 4, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2156

Introduced by Assembly Member Niello

February 21, 2006

An act to amend Section 1209.1 of, and to add Sections 1209.5 and 1269.3 to, the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 2156, as amended, Niello. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services. Existing law makes a violation of these provisions a crime.

Existing law defines a "histocompatibility laboratory director" as any person who is (1) a duly licensed physician, (2) a bioanalyst, or (3) a person who has earned a doctoral degree in a biological science and has completed, as specified, 4 years of experience in immunology, 2 of which have been in histocompatibility testing.

This bill would require an applicant for licensure as a histocompatibility laboratory director, on and after January 1, 2007, to successfully complete a written exam administered by the American Board of Histocompatibility and Immunogenetics and an oral exam administered by the department.

Existing law defines a “laboratory director” as any person that is a duly licensed physician and surgeon or is licensed to direct a clinical laboratory and who meets specified qualifications. Existing law makes laboratory directors responsible for the overall operation and administration of clinical laboratories which includes, among other things, the reporting of results.

This bill would require a laboratory director or a licensed authorized designee appointed by the laboratory director to establish, validate, and document explicit criteria by which clinical laboratory tests or examination results are autoverified, as defined. The bill would also require a laboratory director or an authorized designee, annually, to revalidate the criteria. The bill would require specified licensed persons to be physically present onsite in the clinical laboratory and it would make these specified licensed persons responsible for the accuracy and reliability of the results when they are autoverified and reported.

Under existing law, unlicensed laboratory personnel are authorized to perform specified activities, in a licensed clinical laboratory, under the direct and constant supervision of a physician and surgeon or another licensed person if certain criteria are met. Existing law authorizes these unlicensed laboratory personnel to perform specimen labeling, handling, preservation or fixation, processing or preparation, transportation, and storing.

This bill would authorize a certified pathologists’ assistant, within the specialty of pathology, demonstrating specified competency, to perform specified activities under the ~~direct supervision~~ *supervision and control* of a pathologist. The bill would authorize a pathologists’ assistant, a histologic technician, and a histotechnologist to prepare human surgical specimens for gross description and dissection under the direct supervision, *as defined*, of a qualified pathologist, if ~~they meet~~ *he or she meets* specified requirements. The bill would authorize the department, on and after January 1, 2011, to adopt regulations establishing additional qualification requirements to perform the duties specified in these provisions. ~~The bill would define the term “direct supervision.”~~

Because the bill would revise requirements pertaining to clinical laboratories and their personnel, a violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1209.1 of the Business and Professions
2 Code is amended to read:
3 1209.1. (a) As used in this chapter, “histocompatibility
4 laboratory director” means a person who has completed,
5 subsequent to graduation, four years of experience in
6 immunology, two of which have been in histocompatibility
7 testing, and who meets one of the following requirements:
8 (1) Is a licensed physician and surgeon.
9 (2) Is a bioanalyst.
10 (3) Has earned a doctoral degree in a biological science.
11 (b) On and after January 1, 2007, in order to be eligible for
12 licensure as a histocompatibility laboratory director, an applicant
13 shall provide evidence of satisfactory performance on a written
14 examination in histocompatibility administered by the American
15 Board of Histocompatibility and Immunogenetics, and have
16 demonstrated satisfactory performance on an oral examination
17 administered by the department regarding this chapter and Part
18 493 (commencing with Section 493.1) of Subchapter G of
19 Chapter IV of Title 42 of the Code of Federal Regulations.
20 (c) A person licensed under Section 1260.1 as a
21 histocompatibility laboratory director and qualified under CLIA
22 may perform clinical laboratory tests or examinations classified
23 as of high complexity under CLIA and the duties and
24 responsibilities of a laboratory director, technical consultant,
25 clinical consultant, technical supervisor, and general supervisor,
26 as specified under CLIA, in the specialty of histocompatibility,
27 immunology, or other specialty or subspecialty specified by
28 regulation adopted by the department. A person licensed as a
29 “histocompatibility laboratory director” may perform any clinical
30 laboratory test or examination classified as waived or of
31 moderate complexity under CLIA.

1 SEC. 2. Section 1209.5 is added to the Business and
2 Professions Code, to read:

3 1209.5. (a) “Autoverification” means the use of a computer
4 algorithm in conjunction with automated clinical laboratory
5 instrumentation to review and verify the results of a clinical
6 laboratory test or examination for accuracy and reliability.

7 (b) The laboratory director or authorized designee shall
8 establish, validate, and document explicit criteria by which the
9 clinical laboratory test or examination results are autoverified.

10 (c) The laboratory director or authorized designee shall
11 annually revalidate the explicit criteria by which the clinical
12 laboratory test or examination results are autoverified. The
13 laboratory director shall approve and annually reapprove the
14 computer algorithm.

15 (d) An authorized designee shall be appointed by the
16 laboratory director for the purposes of this section. The
17 authorized designee shall be licensed to engage in clinical
18 laboratory practice pursuant to this chapter and shall be qualified
19 as a clinical consultant, technical supervisor, general supervisor,
20 or technical consultant pursuant to regulations adopted by the
21 department.

22 (e) A person licensed to perform the applicable type and
23 complexity of testing pursuant to Section 1206.5 shall be
24 physically present onsite in the clinical laboratory and shall be
25 responsible for the accuracy and reliability of the results of the
26 clinical laboratory test or examination when the results are
27 autoverified and reported.

28 SEC. 3. Section 1269.3 is added to the Business and
29 Professions Code, to read:

30 1269.3. (a) Notwithstanding Sections 1206.5 and 1269,
31 within the specialty of pathology, a person certified as a
32 pathologists’ assistant by the American Association of
33 Pathologists’ Assistants, the Board of Registry of the American
34 Society for Clinical Pathology, or another national accrediting
35 agency approved by the department, who demonstrates
36 competency to perform all job duties and responsibilities before
37 an assignment to those duties and responsibilities, ~~after~~ *at the*
38 *completion of* six months of performing those duties and
39 responsibilities, and annually thereafter, may perform the

1 following activities under the ~~direct supervision~~ *supervision and*
2 *control* of a pathologist:

3 (1) Prepare human surgical specimens for gross description
4 and dissection, including, but not limited to, description of gross
5 features and selection of tissues for histological examination.

6 (2) Prepare and perform human postmortem examinations,
7 including, but not limited to, selection of tissues and fluids for
8 further examination.

9 (3) Gather other information necessary for an autopsy report.

10 (4) Prepare a body for release.

11 (b) Notwithstanding Section 1206.5 or subdivisions (b), (c),
12 and (d) of Section 1269, the following persons may prepare
13 human surgical specimens for gross description and dissection
14 under the direct supervision of a qualified pathologist, including,
15 description of gross features and selection of tissues for
16 histological examination, if they meet the requirements specified
17 in subdivision (a) of Section 1269 and the minimum education
18 and training requirements for high complexity testing personnel
19 under the CLIA:

20 (1) A pathologists' assistant who does not meet the
21 certification requirements of subdivision (a).

22 (2) A histologic technician.

23 (3) A histotechnologist.

24 (c) For the purposes of ~~this subdivision~~ *subdivision (b)*, direct
25 supervision means that a qualified pathologist shall be physically
26 present onsite in the vicinity of the clinical laboratory where the
27 specialty of pathology is performed and shall be available for
28 consultation and direction during the time the personnel specified
29 in ~~subdivisions (a) and~~ *subdivision (b)* are engaged in the
30 processing of specimens that involve dissection. For tissue
31 processing that does not involve dissection, a qualified
32 pathologist may be available by telephone or other electronic
33 means.

34 (d) A histologic technician or histotechnologist who meets the
35 requirements specified in subdivision (a) of Section 1269, may
36 accession specimens, perform maintenance of equipment, stain,
37 cover slip, label slides, and process tissues by embedding in
38 paraffin or performing microtomy.

1 (e) On and after January 1, 2011, the department may adopt
2 regulations establishing additional qualification requirements to
3 perform the duties described in this section.

4 SEC. 4. No reimbursement is required by this act pursuant to
5 Section 6 of Article XIII B of the California Constitution because
6 the only costs that may be incurred by a local agency or school
7 district will be incurred because this act creates a new crime or
8 infraction, eliminates a crime or infraction, or changes the
9 penalty for a crime or infraction, within the meaning of Section
10 17556 of the Government Code, or changes the definition of a
11 crime within the meaning of Section 6 of Article XIII B of the
12 California Constitution.